UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARC ALIZON,
FRANCOIS BARRE SINOUSSI, PIERRE SONIGO,
PIERRE TIOLLAIS, JEAN-CLAUDE CHERMANN,
LUC MONTAGNIER, and SIMON WAIN-HOBSON

Appeal No. 2005-0398
Application No. 08/384,248

HEARD: April 19, 2005

Before WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 34-36, all the claims remaining in the application. The claims read as follows:

34. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site KpnI at about coordinate 6100 to the restriction site BglII at about coordinate 9150 of plasmid λ-J19; and

(b) raising antibodies against said antigen.

35. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site KpnI at about coordinate 3500 to the restriction site BglII at about coordinate 6500 of plasmid λ-J19; and

(b) raising antibodies against said antigen.

36. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site PstI at about coordinate 800 to the restriction site KpnI at about coordinate 3500 of plasmid λ-J19; and

(b) raising antibodies against said antigen.

Claims 34-36 stand rejected under 35 U.S.C. § 112, first paragraph (written description). We affirm.

Background

The present invention is directed to a method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1). As seen, each of the claims on appeal require two active, manipulative steps, i.e., providing a specified antigen of HIV-1 and raising antibodies against that antigen.

The technology described in the specification relates to "cloned DNA sequences hybridizable to genomic RNA and DNA of lymphadenopathy-associated virus (LAV), a process for their preparation and their uses." Specification, page 1.[1] The nucleic acid

[1] At some point in time, LAV was renamed HIV-1. While the specification of this application refers to LAV, the claims on appeal refer to HIV-1. Consistent with the usage of HIV-1 in the claims

fragments which encode the antigens required by the claims on appeal are described, inter alia, in the specification at pages 3-5. A number of uses for the described nucleic acid fragments are also described in the specification. For example, probes can be designed as diagnostic tools. Specification, page 12. Importantly, appellants state:

> The DNA according to the invention can be used also for achieving the expression of LAV viral antigens for diagnostic purposes as well as for the production of a vaccine against LAV. Of particular advantage in that respect are the DNA fragments coding core (gag region) and for envelope proteins, particularly the DNA fragment extending from Kpn I (6 100) to BglII(9 150).

Specification, page 13, lines 11-17.

The only mention of antibodies in the specification is in the context of using antibodies against HIV-1 antigens to identify antigenically competent fusion proteins produced by recombinant procedures. Specification, page 13, lines 26-31.

Discussion

A. Claim Construction.

Prior to turning to the merits of the written description issue, it is important to understand the scope of the claims on appeal. In relevant part, each of claims 34-36 require "providing an antigen of HIV-1." Subsequently, each claim contains a "wherein" clause which specifies that the antigen is encoded by a specified nucleic acid fragment. In considering the scope of these claims it must be kept in mind that antigens can be "provided" through recombinant methods such as those described in the present

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under review, we shall refer to the virus as HIV-1.

specification or may be "provided" through use of an intact HIV-1 virus. A natural consequence of HIV-1 multiplying within a human body is expression of antigens that provoke the raising of antibodies in the human body by way of the immune system. There is no dispute on this record that each of the antigens required by claims 34-36 are naturally expressed in a human infected by HIV-1 and that the infected individual would raise antibodies against these antigens as the immune system is activated in response to the infection.

We find no language in any of claims 34-36 that distinguishes the claimed methods of producing antibodies from antibody production which will naturally occur in a human that is infected with HIV-1. Importantly, claims 34-36 are not limited to "providing" the antigens in the form of isolated proteins or polypeptides apart from their natural occurrence in HIV-1.

B. Written Description.

A review of the original disclosure reveals that the subject matter set forth in claims 34-36 on appeal was not explicitly described at the time this application was filed. This does not mean that claims 34-36 lack written description. Eiselstein v. Frank, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) ("[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims . . .."). However, "[t]he applicant must . . . convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111,

1117 (Fed. Cir. 1991)(emphasis in original). Thus, the analysis becomes whether the as filed application conveys to those skilled in the art that applicants were in possession of the method of producing antibodies to an antigen of HIV-1 as set forth in claims 34-36.

The position outlined in the Appeal Brief received September 27, 1999, is six-fold.

- The specification literally describes the three restriction fragments recited in claims 34-36.
- The specification literally describes proteins and polypeptides encoded by the three restriction fragments.
- The specification literally describes a need for antibodies against the HIV-1 proteins and polypeptides of the invention.
- The specification literally describes the use of the proteins and polypeptides as HIV-1 antigens.
- The step of "raising antibodies" required by claims 34-36 is embodied in the disclosure in the use of the HIV-1 proteins and polypeptides as "antigens."
- Description of the use of the proteins and polypeptides as "immunogens" resolves any doubt that the specification describes the step of "raising antibodies."

In our view, the first four points made by appellants only establish that there was a need for antibodies to HIV-1 at the time of the present invention and that the materials necessary to raise such antibodies were described in the original disclosure of this application. However, this does not mean that appellants described the method set forth in claims 34-36 to be part of their invention. Rather, we view these disclosures as establishing that it might have been obvious to a person of skill in the art that one could use the nucleic acid fragments described in this application to provide an HIV-1 antigen which then could be used to raise antibodies. However, "[o]ne shows that one

is 'in possession' of the invention by describing the invention, with all its claim limitations, not that which makes it obvious." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

That appellants did not consider methods of making antibodies to HIV-1 to be part of their invention when they filed the application is further evidenced by the sole reference to antibodies in the as-filed specification. As noted above, the only disclosure of antibodies in the specification is in the context of screening recombinant fusion proteins with antibodies against HIV-1 antigens. Specification, page 13, lines 26-32. This portion of the specification casually mentions antibodies against HIV-1 and does not indicate in any manner that methods of making antibodies against HIV-1 were part of the present invention. Rather, in our view, this portion of the specification indicates that appellants envisioned using prior art HIV-1 antibodies to implement this aspect of their invention, not that part of their invention was the discovery that antibodies can be raised against HIV-1 antigens as now claimed.

Nor do we find the last two points made by appellants in regard to the step of raising antibodies required by claims 34-36 being embodied in appellants' disclosure of the use of HIV-1 proteins and polypeptides as antigens or immunogens establish that they were in possession of the invention set forth in claims 34-36. Appellants argue that "an antigen involves the production of antibodies that bind to it; expressed another way, an antigen can be used to raise antibodies to itself." Appeal Brief, page 15. In similar fashion, appellants argue that "the HIV-1 antigens encoded by the three restriction fragments are useful as 'immunogens,' knowing that immunogens are

characterized in the art of immunology by their ability to induce adaptive immunity in an animal, and recognizing that adaptive immunity in the animal involves 'raising antibodies,' . . .." Id., page 19.

In our view, these latter two points at best indicate that it would have been obvious to form antibodies, not that appellants considered methods of raising antibodies to be part of their invention or that they were in any manner "in possession" of such a method. Furthermore, appellants' explanation of adaptive immunity set forth on pages 17-20 of the Appeal Brief confirms that the methods set forth in claims 34-36 are in fact prior art methods, not methods that are inventive to appellants. As we have construed the claims above, claims 34-36 include within their scope providing the needed antigen of HIV-1 by way of an intact living virus. It cannot be gainsaid that at the time of the present invention, humans were infected with HIV-1. As explained by appellants, such individuals would necessarily raise antibodies in response to HIV-1 infection. It strains credulity to think that appellants were unaware at the time of the present invention that prior art individuals infected with HIV-1 were not "raising antibodies" against HIV-1 by way of adaptive immunity. This is further evidence that appellants did not consider the methods that are now claimed in claims 34-36 to be part of their invention at the time of filing. Rather, the evidence of record indicates that these methods were prior art methods and not inventive to appellants.

In reviewing appellants' position we are reminded of the court's observation in Vas-Cath, 935 F.2d at 1561, 19 USPQ2d at 1115, that "[a]dequate written description of the invention guards against the inventor's overreaching by insisting that he recount

his invention in such detail that his future claims can be determined to be encompassed within his original creation." (quoting Rengo Co. V. Molins Mach. Co., 657 F.2d 535, 551, 211 USPQ 303, 3321 (3d Cir. 1981). Here, we find that appellants are overreaching in their attempt to obtain patent protection on the subject matter of claims 34-36.

We have reviewed the Reply Brief filed February 16, 2000, and find that it repeats the arguments set forth in the Appeal Brief which have been answered above. Thus, no separate response to the Reply Brief is needed.

We have also considered the Supplemental Reply Brief received on May 10, 2004, in response to the Supplemental Examiner's Answer mailed March 12, 2004 (Paper No. 47). In stating the rejection in the Supplemental Examiner's Answer, the examiner first asserts that "[c]omplete nucleotide sequences for these various clones were not provided" and that the disclosure "does not describe the isolation and purification of a single [HIV-1] viral immunogen/antigen." Supplemental Examiner's Answer, page 5.

Appellants question the examiner's premise that the nucleotide sequence information provided in the specification is inaccurate or that the nucleic acid fragments may be defective. Id., pages 3-6. We believe this issue is moot when the scope of the claims under review is taken into account. As set forth above, the claims include within their scope the natural process of raising antibodies when an individual is infected by HIV-1.

The next point made in the Supplemental Reply Brief is in regard to the examiner's so-called requirement for a working example of an antibody. Id., pages 6-9. We agree with appellants that a working example is not needed in order to provide written descriptive support for a claimed invention. However, as outlined above, the original disclosure of this application does not provide evidence that appellants were in possession of the invention now claimed, the methods set forth in claims 34-36. At best, the original disclosure of this application provides an outline as to how one could go about making antibodies to HIV-1 if one so desired and even at that, those disclosures are in the context that the prior art already embodied or itself possessed methods of raising antibodies to HIV-1.

The examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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